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EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/656,055	YAVER ET AL.	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 August 2005 and 25 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-81* is/are pending in the application.

4a) Of the above claim(s) *2-10,12-26,28-33,35,37-41 and 44-81* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,11,27,34,36,42 and 43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I in the reply filed on August 17, 2005 is acknowledged. The traversal is on the ground(s) that it would not be a burden to search all bacteria. This is not found persuasive because in the instant case the bacterial species are unrelated and distinct. Furthermore the species have a separate status in the art as shown by their different classification. As such, it would be burdensome to search the bacteria together. A search for the invention of the bacterium would not be coextensive because a search indicating that one bacterial species is novel or unobvious would not extend to a holding that the process of the other is novel or unobvious. For instance, the use of a single sequence is selected from the plurality of sequences obtained from *Bacillus subtillis* in a method for determining the mode of action of an antimicrobial compound, is not necessary to practice the other methods. Because of the different classifications of each group based upon the distinct method steps and use of specific species, a serious burden is imposed on the examiner to perform a complete search of the defined areas in both the patent and non-patent literature. Therefore, because of the reasons given above, the restriction set forth is proper and not to restrict would impose a serious burden on the examination of this application. The requirement is still deemed proper and is therefore made FINAL.

2. Claims 2-10, 12-26, 28-33, 35, 37-41 and 44-81 have been withdrawn from consideration. Claims 1, 11, 27, 34, 36, 42 and 43 are under consideration in this office action.

Information Disclosure Statement

3. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specification

4. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1, 11, 27, 34, 36, 42 and 43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The claims are drawn to a method for determining the mode of action of an antimicrobial compound, comprising: a) detecting hybridization complexes formed by contacting at least one nucleic acid sample, obtained by culturing bacterial cells in the presence of at least one subinhibitory amount of an antimicrobial compound having an unknown mode of action, with a plurality of nucleic acid sequence corresponding to genes of the bacterial cells, wherein the presence, absence or change in the amount of the hybridization complexes detected, compared with hybridization complexes formed between the plurality of nucleic acid sequences and a second nucleic acid sample obtained from the bacterial cells cultured in the absence or presence of a standard compound having a known mode action, is indicative of the similarity or dissimilarity of the mode of actions of the antimicrobial compound and the standard compound; and b) assigning a mode of action for the antimicrobial compound based on the similarity or dissimilarity of values assigned to the hybridization complexes detected in (a) based on the hybridization complexes formed from the second nucleic acid sample.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572,41 USPQ2d 1961, 1966 (1997); *In re Gostelli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood,*107 F.3d at 1572, 41 USPQ2d at 1966." *Regents of the University of California v. Eli Lilly & Co.,* 43 USPQ2d 1398.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP 2163.

Furthermore, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.,* the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials. *Fiers*, 984 F.2d at 1171, 25 USPQ2d at 1606; *In re Smythe*, 480

F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus. . . ."). *Regents of the University of California v. Eli Lilly & Co.,* 43 USPQ2d 1398.

The instant specification and claims are encompassing currently unidentified nucleic acid molecules and claiming that these nucleic acids have the capability of hybridizing to a plurality of nucleic acids sequences. Therefore, there is evidence that claimed nucleic acids have not yet been identified. Moreover, the instant specification fails to disclose the specific nucleic acid molecules; rather the specification broadly defines the sequences to be any nucleic acid molecule of a *Bacillus subtilis* origin, without any discretion. In view of the lack of evidence, it is apparent that Applicants were not in possession of all or many nucleic acid molecules in the presence of at least one subinhibitory amount of an antimicrobial compound having an unknown mode of action, that hybridize with a plurality of nucleic acid sequence corresponding to genes of the bacterial cells at the time of filing the instant application. The specification and claims lack sufficient written description of the generically claimed isolated nucleic acid molecule of a *Bacillus subtilis* origin comprising a nucleotide sequence capable of hybridizing to a nucleotide sequence. The specification does not place any structural, chemical or absolute functional limitations on the nucleic acid molecule per se. The recitation of a nucleic acid sample does not convey a common structure or function. The scope of the claims includes numerous structural variants and the genus is highly variant because a significant number of structural differences between the genus members are permitted. The specification fails to provide guidance on the structure of the nucleic acid samples. Structural features that could distinguish molecules in the genus from others in the class are missing from the disclosure and the claims. No common structural attributes identify the members of the genus. The general

knowledge and level of skill in the art do not supplement the omitted description, because specific, not general guidance is needed.

With respect to claims 36 and 42, the claims are drawn to homologs thereof. And as stated above, the instant specification fails to disclose the specific nucleic acid molecules or the homologs thereof. The specification has not identified any homologs thereof. There is no teaching of the identification or isolation of homologs thereof. The specification and claims lack sufficient written description of the generically claimed homologs thereof. The specification does not place any structural, chemical or absolute functional limitations on the homologs thereof. The recitation of homologs thereof does not convey a common structure or function. The scope of the claims includes numerous structural variants and the genus is highly variant because a significant number of structural differences between the genus members are permitted. The specification fails to provide guidance on the structure of the homologs thereof. Structural features that could distinguish molecules in the genus from others in the class are missing from the disclosure and the claims. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description, because specific, not general guidance is needed. In view of the lack of evidence, it is apparent that Applicants were not in possession of homologs thereof.

The skilled artisan cannot envision the detailed structure of a nucleic acid of bacterial origin comprising a nucleotide sequence capable of hybridizing to a plurality of nucleic acid sequences, thus conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation.

The nucleic acid molecule comprising one or more nucleic acids is defined by its activity of function, i.e., the ability to hybridize to the plurality of sequences. While the

description of the ability of the claimed nucleic acid molecule which hybridizes may generically describe the nucleic acid molecule's function, it does not describe the nucleic acid molecule itself. The hybridization capability distinction is a purely functional distinction. Thus, a description of the nucleic acid molecule by what it does, such as hybridizing to a plurality to sequences is insufficient. Since the disclosure fails to describe the common attributes or structural characteristics that identify the members of the genus, and because the genus of nucleic acid molecules of bacterial or even *Bacillus subtilis* origin is highly variable, the function of hybridization alone is insufficient to describe the genus of nucleic acid molecules.

An adequate description requires more than a mere statement that it is part of the invention. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016. Encoding distinguishes the claimed nucleotide sequences from unclaimed sequences only by what they do, which is a purely functional distinction. Even where there is an actual reduction to practice, which may demonstrate possession of an embodiment of an invention, it does not necessarily describe what the claimed invention is. The instant claims describe a nucleic acid molecule described by its function i.e., hybridization or being a homolog, however this description does not describe the claimed nucleic acid molecules themselves. See also, *In The Reagents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), where the court held that a generic statement that defines a genus of nucleic acids by only their functional activity does not provide an adequate description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus.

At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention". Thus, in the absence of an isolated nucleic acid molecule of a bacterial origin comprising a nucleotide sequence hybridizing to a plurality of sequences described only by its ability to hybridize fails to meet the written description requirements.

Therefore the written description is not commensurate in scope with the claims drawn to fragments thereof. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115). Thus, the skilled artisan cannot envision the detailed structure of the fragments thereof, thus conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. An adequate description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. Furthermore, *In The Reagents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus by only their functional activity does not provide an adequate description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of molecules falling within the scope of the claimed genus. This demonstration is required for the skilled artisan to be able to use the claimed composition for its intended purpose. Without this demonstration, the skilled artisan would not be able to reasonably predict the structure of the claimed nucleic acid samples, sequences or homologs. Thus a skilled artisan would be required to *de novo* locate, identify and characterize the claimed method. Therefore, the claims fail to meet the written description requirements.

6. Claims 1, 11, 27, 34, 36, 42 and 43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) The terms "subinhibitory amount" and “similarity or dissimilarity” in claim 1 are relative terms which renders the claim indefinite. The terms are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Neither the claims nor the specification teach the metes and bounds of amount equal a subinhibitory amount and what amounts do not. Similarly, the metes and bounds of what is similar or dissimilar are relative and there is no criteria which defines how to determine whether something is similar or not. Moreover, the criteria of what determines whether. Thus the claim is unclear and appropriate clarification is required to overcome the rejection.

b) The term "significantly different " in claim 36 is a relative term which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Neither the claims nor the specification teach the metes and bounds of detected levels of expression are deemed significantly different and what levels are not different. Moreover, it is unclear what criterion is being used to define significantly different. Thus the claim is unclear and appropriate clarification is required to overcome the rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 11 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Zhang et al.

The claims are drawn to a method for determining the mode of action of an antimicrobial compound, comprising: a) detecting hybridization complexes formed by contacting at least one nucleic acid sample, obtained by culturing *Bacillus subtilis* bacterial cells in the presence of at least one subinhibitory amount of an antimicrobial compound having an unknown mode of action, with a plurality of nucleic acid sequence corresponding to genes of the bacterial cells, wherein the presence, absence or change in the amount of the hybridization complexes detected, compared with hybridization complexes formed between the plurality of nucleic acid sequences and a second nucleic acid sample obtained from the bacterial cells cultured in the absence or presence of a standard compound having a known mode action, is indicative of the similarity or dissimilarity of the mode of actions of the antimicrobial compound and the standard compound; and b) assigning a mode of action for the antimicrobial compound based on the similarity or dissimilarity of values assigned to the hybridization complexes detected in (a) based on the hybridization complexes formed from the second nucleic

acid sample. The dependant claims are drawn to action of the antimicrobial compound and the source of the plurality of nucleic acids.

Zhang et al., teach regulated gene expression in *Staphylococcus au*reus for identifying antibiotic mode of action. The selective modulation of gene expression levels is a very powerful strategy and allows for the gaining of valuable information (page 297). Regulated gene expression is useful for studying gene function and evaluating molecular targets for antibiotic discovery (page 297). Well-regulated gene control systems have been use of *Escherichia coli* and *Bacillus subtilis* (page 297). Thus, the authors demonstrate that the sequences can be obtained from *Bacillus subtilis,* just as required by the claims. Zhang et al., demonstrates how modulating target expression levels is linked to the antibacterial activity of selected compounds with their proposed cellular target (page 298). Section 3.3 teaches the examination of antibiotic mode of action (page 302). The authors identified an actininin-like compound which inhibits protein synthesis in bacteria by preventing the removal of the N-formyl group from newly synthesized polypeptides (page 302-3). Thus the antibacterial compound is a member of the class of compounds which inhibit protein synthesis, just as required by the claims. The compound was contained in media which also comprised the bacterial cells (page 304). Thus, Zhang et al., teach that the bacterial cells were cultured in the presence of at least one subinhibitory amount of an antimicrobial compound having an unknown mode of action just as required by the claims. Zhang et al., teach hybridization techniques via PCR and Western blotting as a means for assessing gene expression (page 304). The PCR techniques teach the hybridization of

at least one nucleic acid hybridizing to the nucleic acids within the plurality of nucleic acid sequences. The hybridization complexes were detected by western blotting teachings, just as required by the claims. Therefore the art teaches hybridization as the means for analyzing gene expression just as the claims require. The results compare the unknown compound against another well-known antibiotic, mupirocin, which acts as the standard. See also Table 1 (page 304). Therefore Zhang et al., teach culturing and detection of hybridized complexes in the absence or presence of a known of standard compound having a known mode of action just as required by the claim. The comparison allows for the authors to conclude that the antibacterial activity of the compound appears to be due to its inhibition of the target enzyme (page 304). Thus, the art teaches that the comparison between the unknown and known modes of action are indicative or similarities or dissimilarities of the modes of action of between the two, just as required by the claims.

Therefore, Zhang et al., teach a method for determining the mode of action of an antimicrobial compound, comprising: a detection of hybridization complexes from *Bacillus subtilis*, a comparison of the hybridization complexes to a standard compound having a known mode action, and assigning a mode of action for the unknown antimicrobial compound based on the similarity or dissimilarity of values assigned to the hybridization complexes detected from the known sample.

8. Claims 1, 11, 34, 36 and 42-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilson et al.

The claims are drawn to a method for determining the mode of action of an antimicrobial compound, comprising: a) detecting hybridization complexes formed by contacting at least one nucleic acid sample, obtained by culturing bacterial cells in the presence of at least one subinhibitory amount of an antimicrobial compound having an unknown mode of action, with a plurality of nucleic acid sequence corresponding to genes of the bacterial cells, wherein the presence, absence or change in the amount of the hybridization complexes detected, compared with hybridization complexes formed between the plurality of nucleic acid sequences and a second nucleic acid sample obtained from the bacterial cells cultured in the absence or presence of a standard compound having a known mode action, is indicative of the similarity or dissimilarity of the mode of actions of the antimicrobial compound and the standard compound; and b) assigning a mode of action for the antimicrobial compound based on the similarity or dissimilarity of values assigned to the hybridization complexes detected in (a) based on the hybridization complexes formed from the second nucleic acid sample. The dependant claims are drawn to action of the antimicrobial compound, the sequences being contained on a substrate, and the method further comprising an identification and isolation step.

Wilson et al., teach exploring drug-induced alterations in gene expression in *Mycobacterium tuberculosis* by microarray hybridization. Drugs and compounds selectively induce changes in the transcription of genes, and the resulting gene expression profile would serve as a signature of the inhibitor used especially in cases of inhibitors whose modes of action were unknown (page 12,833). Thus the ability for

pathway characterization is available because complete genome sequences are known and microarrays containing representatives of each of the genes are known (page 12,833). Here the authors generated a response of isoniazid (INH) a drug that interrupts the synthesis of mycolic acids which affects the waxy outer lipid envelope of mycobacteria. Thus the antimicrobial compound is a member of the class of compounds which interferes with the cell membrane, just as required by the claims. This system provides the framework for interpreting the transcriptional responses that we would detect by the microarray and allow for comparison with published results of genes and proteins that are known to be INH induced (page 12,833). Wilson et al., teach the preparation of DNA microarrays which contains genomic sequences and fragments (page 12,834). The array contains the plurality of sequences is contained on a substrate, just as required by the claims. Wilson et al., teach the growth and drug treatment of the bacterial strains with the drug (page 12,834). The authors teach culturing the cells in the presence of at least one subinhibitory amount of an antimicrobial compound just as required by the claims. The authors also teach microarray hybridization where the DNA was applied to the array in a hybridization mixture which allowed hybridization to occur (page 12,835). The detection of hybridization complexes formed by contacting at least one nucleic acid with a plurality of nucleic acid sequences corresponding to genes of the bacterial cells has been taught. The microarray hybridization provide a characteristic signature for the cellular processes that are affected by the compound (page 12,838). The drug response profiles were distinct from the profiles obtained from bacteria exposed in a similar manner to a variety

of different compounds (page 12,838). Thus the authors teach the comparison with hybridized complexes formed between the plurality of nucleic acid sequences and a second nucleic acid sample obtained from bacterial cells cultured in the absence or presence of a standard compound having a known mode if action, just as required by the claims. The profiles provided are indicative of the similarity or dissimilarity of the mode of actions of the antimicrobial compound and the standard compound, just as required by the claims. Wilson et al., also identified at least one sequence from the genes which encode the KatG complex that has a level significantly different from bacterial cells not in the presence of INH, just as required by the claims (page 12,837). The results show that the characteristic drug response is the result of intracellular conditions associated with the drugs mode of action (page 12,838). Thus it is possible to predict the mode of action of a novel compound based on a physiologically derived interpretation of its expression response to that compound (page 12,838). Therefore, the prior art teaches assigning a mode of action for the antimicrobial compound based on the similarity or dissimilarity to the hybridization complexes detected and based on the hybridization complexes from a known or standard, just as required by the claims.

Therefore, Wilson et al., teach a method for determining the mode of action of an antimicrobial compound, comprising: a detection of hybridization complexes, a comparison of the hybridization complexes to a standard compound having a known mode action, and assigning a mode of action for the unknown antimicrobial compound based on the similarity or dissimilarity of values assigned to the hybridization complexes detected from the known sample.

Prior Art

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Gmuender et al., teach the combined transcription and translation analysis by gene expression changes triggered by exposure of *Haemophilus influenzae* to novobiocin or ciprofloxacin.

Conclusion

10. No claims allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
February 8, 2006

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